

## **REMARKS**

### **Status of the Claims**

Claims 1, 4, 7 to 11, and 17 to 20 were amended in connection with this Reply. Claims 5 and 16 are cancelled herein and Claims 2, 3, 6, and 12 to 15 were previously presented. No claims have been added or withdrawn in this paper. Accordingly, presented herein are claims 1 to 4, 6 to 15, and 17 to 20 for the Examiner's consideration.

Amendments to Claims 1, 7, and 8 clarify that the claims are directed to a method of treating schizophrenia in patients without increasing the BMI of the patients being treated. Amendment to Claims 1, 7 is 8 are supported by the specification on Page 8, lines 7 to Page 9, line 12 and the tables on Page 8. Claims 4, 9 to 11, and 17 to 20 were amended to reflect changes in antecedent basis introduced by amendment into the claims from which those claims depend. Accordingly, these amendments are supported by the amendment to the respective claims from which these claims depend.

### **Rejection Under 35 U.S.C. § 112**

The present Action rejects claims 1 to 6 and 13 to 16 under 35 U.S.C. §112 second paragraph on the grounds that the terms "overweight" (in quotation marks) and "propensity to be overweight" (not in quotation marks) appear in the claim. The independent claims in which these terms appear have been amended and no longer contain the terms to which the present Action objects in the form to which an objection was raised. Claim 3 still contains the term "overweight" (not in quotation marks) which term is defined in the specification on Page 3 at lines 29 to 33, which definition accords with the generally accepted medical definition of the term. Accordingly, in view of the present amendment this objection is moot and the Examiner is respectfully requested to enter the amendment and reconsider the claims.

Rejection Under 35 U.S.C. § 103(a)

The present Action rejects Claims 7 to 12 and 17 to 20 pursuant to 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,763,476 to Delbressine et al. (the '476 patent) on the grounds that the '476 patent teaches that asenapine is useful in the treatment of Schizophrenia. The present Action appears to assert this rejection either supported solely by the '476 patent, or in view of a combination of the '476 patent and an article by L.J. Aronne published in J. Clin. Psychiatry 2001, 62 (suppl 23), (the Aronne publication). The present Action asserts that the Aronne publication teaches that patients with schizophrenia are known to have a propensity for being overweight, as the term is medically defined in terms of BMI, to a greater degree than the general population. The Aronne publication states that approved drugs for use in treatment of obesity are neither safe nor effective for the treatment of obesity in patients receiving atypical antipsychotic therapy (first paragraph on Page 19 under the sub-heading "Pharmacotherapy"). Further, the Aronne publication neither mentions asenapine, nor the treatment of schizophrenia, nor describes or suggests treatment of schizophrenia without increasing BMI in a patient population.

The present Action also references U.S. Patent No. 5,496,831 (identified therein as Alexander-Bridges et al.), which defines obesity in terms of BMI, and discusses methods of treating insulin-induced obesity but does not mention asenapine or the treatment of schizophrenia.

As amended, the present claims are directed to a method of treating schizophrenia without causing or exacerbating obesity (as obesity is defined in terms of BMI which the cited references above indicate are standard medical definitions of obesity and overweight in the medical arts) across a patient population receiving treatment.

None of the cited publications describe or suggest that asenapine is useful in the treatment of schizophrenia without increasing BMI in a patient population. This information can only be learned from reading the present specification. Accordingly, the present Action attempts to engage in an impermissible hindsight reconstruction of the cited publications to find obviousness. Moreover, the cited publications don't even supply all of the elements of the claimed invention. Accordingly, it can not be

reasonably said that, in the context of the ordinary level of skill in the art, the amended claims are obvious in view of the cited publications. The Examiner is respectfully requested to enter the amendments presented herein and reconsider the claims.

In view of the foregoing Amendments and Remarks Applicants respectfully request that the Examiner enter the amendments, withdraw the rejections pursuant to 35 U.S.C. §103 and 35 U.S.C. §112 and pass these claims into allowance.

**MISCELLANEOUS**

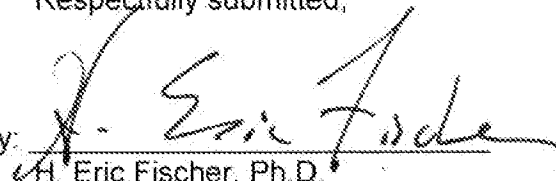
This is a Reply to an Action mailed March 30, 2010, with a three month initial period for Reply ending on June 30, 2010. As this Reply is being submitted electronically prior to July 30, 2010, a one-month extension of the period for Reply, from June 30, 2010 to July 30, 2010, is requested. The commissioner is authorized to charge the fee for the requested one month extension of the Reply period, pursuant to 37 C.F.R. §1.17(a)(1), believed to be \$130.00, to Applicants' Deposit Account No. 50-4205. No other fees are believed to be due in connection with this Reply, however should it be deemed that any additional fees are necessary, the Commissioner is authorized to charge the amount thereof to Applicants' Deposit Account No. 50-4205.

It is believed that the foregoing is fully responsive to the outstanding Action. The Examiner is invited to call the undersigned attorney on any outstanding matter connected with this application.

Respectfully submitted,

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By:



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